REMARKS/ARGUMENTS

Claims 11-36 are active. Claims 1-10 have been cancelled. New claim 33 tracks claim 11, but has been revised to remove the intended use limitation. Claims 34-36 find support on pages 2-4. Conventional peritoneal dialysis solutions were known in the art as indicated in the disclosure and by the attached documents from Baxter Healthcare Corporation. As shown in the original figures, use of a dialysate containing adenosine triphosphate (ATP) reduced peritoneal injuries caused by the high sugar concentrations in conventional peritoneal dialysis solutions not containing ATP. No new matter has been added. Favorable consideration of this amendment and allowance of this case are respectfully requested.

The Applicants thank Examiners Henry and Jiang for the courteous and informative discussion on December 7, 2009. It was indicated that Isono, et al., U.S. Patent No. 5,871,477 did not disclose a dialysis solution containing adenosine triphosphate (ATP). The Examiners responded that Isono, col. 2, line 41 and col. 18, lines 14-15 described solutions containing ATP and that while these solutions were identified as "organ-preserving solutions" (see col. 2, lines 35-36, col. 17, line 36 *ff.*) they were not distinguishable from dialysis solutions used in the claimed methods. No agreement was reached on this point.

The Applicants urged that Isono primarily involved a "medical container with an electrolyte stored therein" (col. 1, lines 8-9) and merely described a variety of different types of conventional physiological solutions for inclusion in the medical container. While these include conventional infusion solutions, dialysis solutions, and electrolyte solutions (col. 1, lines 10-14), the Applicants ruged that there was no suggestion to make a dialysis solution containing ATP,

nor any suggestion of a dialysis method using a dialysis solution containing ATP. The Examiners pointed out that Fig. 13 of Isono discloses a method of dialysis and requested that the Applicants explain this figure in the context of the invention as well as point out other possible distinctions between the ATP-containing solutions of Isono and those used by the claimed method in their next response.

Rejection—35 U.S.C. §103(a)

Claims 11-32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Isono, et al., U.S. Patent No. 5,871,477. This rejection is respectfully traversed, because Isono, et al. does not disclose or suggest all the elements of the invention:

(1) a peritoneal dialysis solution containing adenosine triphosphate, or

(2) the step of administering a peritoneal dialysis solution containing adenosine triphosphate to a patient.

Isono also did not provide:

(3) a reasonable expectation of success that administering a peritoneal dialysis solution containing ATP would ameliorate damage caused by hyperosmotic sugar concentration in conventional peritoneal dialysis solutions to the mesothelial cells which line the peritoneum.

With respect to point (1) above, as discussed in the Applicants prior responses, Isono does not disclose a peritoneal dialysis solution. Those of ordinary skill in the art understand that peritoneal dialysis solutions have particular osmotic and compositional characteristics that permit them to function

in methods of dialysis. These include hyperosmotic properties conferred by the relatively high sugar concentrations needed to perform peritoneal dialysis.

On the other hand, while Isono describes conventional dialysis solutions that do not contain ATP (see col. 2, lines 5-33) and depicts conventional methods of dialysis in Fig. 13, it does not disclose or suggest adding ATP to a dialysis solution.

Rather, Isono discloses "organ-preserving solutions" that may optionally include "adenosine triphosphate" or optionally contain numerous other types of drugs and compounds useful for organ preservation, see the list in col. 2, lines 35-47. Moreover, the exemplary organ-preservation solution of Isono (col. 2, lines 26-34) contains heparin--an ingredient missing from the exemplary peritoneal dialysis solution in col. 2, lines 9-17--and unlike the conventional dialysis solution is devoid of a glucose (or indeed any hyperosmotic concentration of sugar).

The Office's conflation of a dialysis solution with an organ-preservation solution is improper and cannot support a *prima facie* basis for an obviousness rejection. While the Official Action ("OA") explicitly states that "Isono et al.'s composition does not contain adenosine triphosphate" (OA, bottom of page 3), it contends that such a dialysis solution is suggested by Isono. However, Isono clearly distinguishes amongst the different physiological solutions that may be contained within the medical container it discloses. Namely, cols. 1 and 2 of Isono distinguish between (i) infusion solutions, (ii) dialysate, and (iii) an organ (tissue) preserving solution, see col. 1, lines 21-24, and col. 1, lines 51-col. 2, line 4 describing infusion solutions, col. 2, lines 5-21 which disclose dialysates, and col. 2, lines 35-47 which describe organ-preserving solutions. It is evident from

these portions of the reference that Isono recognized the significant compositional differences between a peritoneal dialysis solution and one used to preserve organs.

Based on these distinctions and the level of ordinary skill in the medical arts, one would not have used an organ preservation solution to perform peritoneal dialysis. This clearly would not be accepted by those of ordinary skill in the art and would, in fact, subject any medical practitioner using an organ-preservation solution for peritoneal dialysis (or *vice versa* using a dialysis solution to preserve an organ) to serious claims of medical malpractice.

With regard to point (2) above, since col. 2 of Isono does not suggest a peritoneal dialysis solution containing adenosine triphosphate, it also cannot suggest the claimed method of performing peritoneal dialysis with a solution containing ATP. Isono suggests that ATP might be one ingredient useful in an "organ preservation" solution, but does not suggest and fails to recognize the value of ATP in a peritoneal dialysis solution. Assuming *arguendo*, that Isono did suggest a peritoneal dialysis solution containing adenosine triphosphate (ATP), which it does not, it provided no suggestion select such a dialysate for the treatment of peritoneal injury or cell injury caused by sugar.

Page 4, lines 7-9 of the OA state that "One of ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate". However, the Examiner has not pointed out any support for this alleged motivation in Isono. As noted above, Isono only describes adenosine triphosphate in the context of an organ-preserving solution, not for use as in a peritoneal

dialysis solution. The Examiner has not pointed out any other portion of Isono suggesting administering "a dialysate comprising adenosine triphosphate" to a patient having a peritoneal injury or cell injury caused by sugar" as required by independent claim 11. Furthermore, adenosine triphosphate is not recognized as a conventional component of dialysis solution as evident from the citations below:

(1) Wikipedia (last modified on 2 January 2010 at 18:56; http://en.wikipedia.org/wiki/Peritoneal_dialysis; entry attached):

> **Peritoneal dialysis** (PD) is a treatment for patients with severe chronic kidney failure. The process uses the patient's peritoneum in the abdomen as a membrane across which fluids and dissolved substances (electrolytes, urea, glucose, albumin and other small molecules) are exchanged from the blood. Fluid is introduced through a permanent tube in the abdomen and flushed out either every night while the patient sleeps (automatic peritoneal dialysis) or via regular exchanges throughout the day (continuous ambulatory peritoneal dialysis). PD is used as an alternative to hemodialysis though it is far less common. It has comparable risks and expenses, with the primary advantage being the ability to undertake treatment without visiting a medical facility. The primary complication with PD is a risk of infection due to the presence of a permanent tube in the abdomen.

(ii) Package insert from Baxter U.S. describing components of a peritoneal dialysis solution:

http://www.baxter.com/products/renal/peritoneal_dialysis/sub/solutions.html (last accessed August 5, 2009; attached).

(iii) Technical literature from Baxter Healthcare Corporation (attached).

Therefore, even if, for the sake of argument, Isono disclosed a peritoneal dialysis solution containing one of the ingredients used to prepare organ-preservation solutions, such as adenosine triphosphate, it did not suggest treatment of the class of patients required by the invention using such a composition or that selection of ATP would provide any benefit.

Furthermore, with regard to point (3) above, Isono cannot provide a reasonable expectation of success for the invention which as shown by the experimental data of record reduces peritoneal injury caused by glucose by incorporating ATP. For example, Fig. 1 shows that inclusion of adenosine triphosphate alleviates the decreased viability of peritoneal mesothelial cells caused by increasing sugar concentrations; see also the top of page 10 of the specification. Fig. 2 shows that substitution of adenosine for adenosine triphosphate (ATP) did not alleviate the decrease in peritoneal mesothelial cell viability. This indicates the importance of the selection of ATP. Figs. 3-5 show that the viability increasing effect of ATP is inhibited by adenosine triphosphate antagonists, again showing the importance of selecting ATP. Isono does not provide a reasonable expectation that inclusion of adenosine triphosphate (ATP) in a dialysate would provide this superior effect.

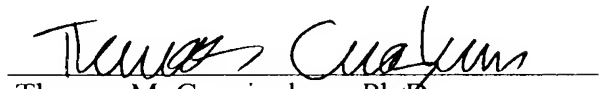
This rejection is improper because Isono does not (i) teach all the elements of the invention, namely a peritoneal dialysate solution containing adenosine triphosphate and the step of administering such an ATP-containing solution to a patient in need of peritoneal dialysis, (ii) does not suggest using a dialysate containing adenosine triphosphate to ameliorate peritoneal damage or cell injury caused by sugar, and (iii) does not provide a reasonable expectation of success for treating a peritoneal injury caused by sugar using such a method. Therefore, taking into account all of these reasons, as well as the experimental and technical data of record, this rejection cannot be sustained.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



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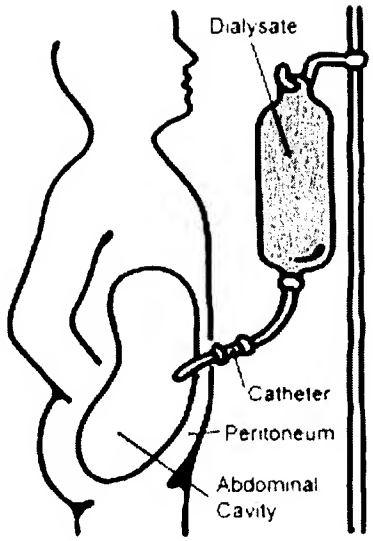
(OSMMN 08/07)

Peritoneal dialysis

From Wikipedia, the free encyclopedia

Peritoneal dialysis (PD) is a treatment for patients with severe chronic kidney failure. The process uses the patient's peritoneum in the abdomen as a membrane across which fluids and dissolved substances (electrolytes, urea, glucose, albumin and other small molecules) are exchanged from the blood. Fluid is introduced through a permanent tube in the abdomen and flushed out either every night while the patient sleeps (automatic peritoneal dialysis) or via regular exchanges throughout the day (continuous ambulatory peritoneal dialysis). PD is used as an alternative to hemodialysis though it is far less common. It has comparable risks and expenses, with the primary advantage being the ability to undertake treatment without visiting a medical facility. The primary complication with PD is a risk of infection due to the presence of a permanent tube in the abdomen.



Schematic diagram of peritoneal dialysis

Contents

Method

The abdomen is cleaned in preparation for surgery, and a catheter is surgically inserted with one end in the abdomen and the other protruding from the skin. Before each infusion the area must be cleaned, and flow into and out of the abdomen tested. A large volume of fluid is introduced to the abdomen over the next ten to fifteen minutes.[1] The total volume is referred to as a *dwell*[2] while the fluid itself is referred to as dialysate. The dwell can be as much as 2.5 litres, and medication can also be added to the fluid immediately before infusion.[1] The dwell remains in the abdomen and waste products diffuse across the peritoneum from the underlying blood vessels. After a variable period of time depending on the treatment (usually 4-6 hours[1]), the fluid is removed and replaced with fresh fluid. This can occur automatically while the patient is sleeping (automated peritoneal dialysis, APD), or during the day by keeping two litres of fluid in the abdomen at all times, exchanging the fluids four to six times per day (continuous ambulatory peritoneal dialysis, CAPD).[2][3]


Hookup


Infusion

The fluid used typically contains sodium, chloride, lactate or bicarbonate and a high


Diffusion (fresh)


Diffusion (waste)

percentage of glucose to ensure hyperosmolarity. The amount of dialysis that occurs depends on the volume of the dwell, the regularity of the exchange and the concentration of the fluid. APD cycles between 3 and 10 dwells per night, while CAPD involves four dwells per day of 2-2.5 litres per dwell, with each remaining in the abdomen for 4-8 hours. The viscera accounts for roughly four-fifths of the total surface area of the membrane, but the parietal peritoneum is the more important of the two portions for PD. Two complementary models explain dialysis across the membrane - the three pore model (in which molecules are exchanged across membranes which filter molecules, either proteins, electrolytes or water, based on the size of the pore) and the distributed model (which emphasizes the role of capillaries and the solution's ability to increase the number of active capillaries involved in PD). The high concentration of glucose drives the exchange of fluid from the blood with glucose from the peritoneum. The solute flows from the peritoneal cavity to the organs, and thence into the lymphatic system. Individuals differ in the amount of fluid absorbed through the lymphatic vessels, though it is not understood why. The ability to exchange fluids between the peritoneum and blood supply can be classified as high, low or intermediate. High transporters tend to diffuse substances well (easily exchanging small molecules between blood and the dialysis fluid, with somewhat improved results frequent, short-duration dwells such as with APD) while low transporters filter fluids better (transporting fluids across the membrane into the blood more quickly with somewhat better results with long-term, high-volume dwells such) though in practice either type of transporter can generally be managed through the appropriate use of either APD or CAPD.[4]

Though there are several different shapes and sizes of catheters that can be used, different insertion sites, number of cuffs in the catheter and immobilization, there is no evidence to show any advantages in terms of morbidity, mortality or number of infections, though the quality of information is not yet sufficient to allow for firm conclusions.[5]

Complications

The volume of dialysate removed and weight of the patient are normally monitored; if more than 500ml of fluid are retained or a litre of fluid is lost across three consecutive treatments, the patient's physician is generally notified. Excessive loss of fluid can result in hypovolemic shock or hypotension while excessive fluid retention can result in hypertension and edema. Also monitored is the color of the fluid removed: normally it is pink-tinged for the initial four cycles and clear or pale yellow afterwards. The presence of pink or bloody effluent suggests bleeding inside the abdomen while feces indicates a perforated bowel and cloudy fluid suggests infection. The patient may also experience pain or discomfort if the dialysate is too acidic, too cold or introduced too quickly, while diffuse pain with cloudy discharge may indicate an infection. Severe pain in the rectum or perinium can be the result of an improperly placed catheter. The dwell can also increase pressure on the diaphragm causing impaired breathing, and constipation can interfere with the ability of fluid to flow through the catheter.
[1][1]20389858588/

Risks and benefits

PD is less efficient at removing wastes from the body than hemodialysis, and the presence of the tube presents a risk of peritonitis due to the potential to introduce bacteria to the abdomen;[2] peritonitis is best treated through the direct infusion of antibiotics into the peritoneum with no advantage for other frequently used treatments such as routine peritoneal lavage or use of urokinase.[6] The tube site can also become infected; the use of prophylactic nasal mupirocin can reduce the number of tube site infections,

but does not help with peritonitis.[7] Infections can be as frequent as once every 15 months (0.8 episodes per patient year). Compared to hemodialysis, PD allows greater patient mobility, produces fewer swings in symptoms due to its continuous nature, and phosphate compounds are better removed, but large amounts of albumin are removed which requires constant monitoring of nutritional status. The costs and benefits of hemodialysis and PD are roughly the same - PD equipment is cheaper but the costs associated with peritonitis are higher.[3] There is insufficient research to adequately compare the risks and benefits between CAPD and APD; a Cochrane Review of three small clinical trials found no difference in clinically important outcomes (i.e. morbidity or mortality) for patients with end stage renal disease, nor was there any advantage in preserving the functionality of the kidneys. The results suggested APD may have psychosocial advantages for younger patients and those who are employed or pursuing an education.[8]

Other complications include hypotension (due to excess fluid exchange and sodium removal), low back pain and hernia or leaking fluid due to high pressure within the abdomen. PD may also be used for patients with cardiac instability as it does not result in rapid and significant alterations to body fluids, and for patients with insulin-dependent diabetes mellitus due to the ability to control blood sugar levels through the catheter. Hypertriglyceridemia and obesity are also concerns due to the large volume of glucose in the fluid, which can add as many as 1200 calories to the diet per day.[9] Of the three types of connection and fluid exchange systems (standard, twin-bag and y-set; the latter two involving two bags and only one connection to the catheter, the y-set uses a single y-shaped connection between the bags involving emptying, flushing out then filling the peritoneum through the same connection) the twin-bag and y-set systems were found superior to conventional systems at preventing peritonitis.[10]

Frequency

In a 2004 worldwide survey of patients in end stage renal disease, approximately 11% were receiving PD, compared to the much more common hemodialysis. In the United Kingdom, South Korea and Mexico PD was more common than the world average, with the latter conducting most of its dialysis (75%) through PD.[11]

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External links

- Dialysis (http://www.dmoz.org//Health/Conditions_and_Diseases/Genitourinary_Disorders/Kidney/End_St at the Open Directory Project
- Treatment Methods for Kidney Failure (http://kidney.niddk.nih.gov/kudiseases/pubs/kidneyfailure/index.htm) - National Institute of Diabetes and Digestive and Kidney Diseases

Retrieved from "http://en.wikipedia.org/wiki/Peritoneal_dialysis"
Categories: Medical treatments | Nephrology

<< Back To Peritoneal Dialysis
HOMECHOICE PRO
PD Solutions
RENALSOFT PD Software Module

Peritoneal Dialysis (PD) Solutions

EXTRANEAL (icodextrin)
Peritoneal Dialysis Solution

WHAT IS EXTRANEAL?

EXTRANEAL (icodextrin) peritoneal dialysis solution is ifor use in the long (8 to 16-hour) dextrose, EXTRANEAL can improve long-dwell ultrafiltration and clearance of creatinine high-average or high peritoneal transport characteristics.

Long history of international use

- Clinical experience in more than 30,000 patients in more than 55 countries
- In Europe, approximately 50% of PD patients use EXTRANEAL

For more information on EXTRANEAL (icodextrin), including access to the EXTRANEAL

Clinician Patient

PRESCRIBING INFORMATION

EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) solution is indicated for a single da hour) dwell during Continuous Ambulatory Peritoneal Dialysis (CAPD) or Automated F management of End-Stage Renal Disease (ESRD). EXTRANEAL is also indicated to dextrose) long-dwell ultrafiltration and clearance of creatinine and urea nitrogen in pat greater transport characteristics, as defined using the Peritoneal Equilibration Test (P

IMPORTANT RISK INFORMATION

EXTRANEAL (icodextrin) Peritoneal Dialysis (PD) Solution

Dangerous Drug-Device Interaction

Only use glucose-specific monitors and test strips to measure blood glucose levels in (icodextrin) PD Solution. Blood glucose monitoring devices using glucose dehydroger (GDH PQQ) or glucose-dye-oxidoreductase (GDO)-based methods must not be used based glucose monitors and test strips has resulted in falsely elevated glucose readir maltose and has led patients or health care providers to withhold treatment of hypogl inappropriately. Both of these situations have resulted in unrecognized hypoglycemia consciousness, coma, permanent neurological damage, and death. Plasma levels of return to baseline within approximately 14 days following cessation of EXTRANEAL a elevated glucose levels may be measured up to two weeks following cessation of EX PQQ or GDO-based blood glucose monitors and test strips are used.

Because GDH PQQ and GDO-based blood glucose monitors may be used in hospita health care providers of peritoneal dialysis patient using EXTRANEAL carefully reviev blood glucose testing system, including that of test strips, to determine if the system i EXTRANEAL (icodextrin) PD Solution.

To avoid improper insulin administration, educate patients to alert health care provide

they are admitted to the hospital.

Information regarding glucose monitor and test strip methodology can be obtained frc
of toll free numbers for glucose monitor and test strip manufacturers, please contact t
HelpLine 1-888-RENAL-HELP or visit www.glucosesafety.com.

EXTRANEAL is contraindicated in patients with a known allergy to cornstarch or icod
intolerance, pre-existing severe lactic acidosis, and in patients with glycogen storage

EXTRANEAL is not for intravenous injection.

Patients with insulin-dependent diabetes may require modification of insulin dosage f

A patient's volume status should be carefully monitored to avoid hyper- or hypovolem
consequences including congestive heart failure, volume depletion and hypovolemic
record must be kept and the patient's body weight monitored.

In clinical trials, the most frequently reported adverse events occurring in ⩾ 5% of pa
EXTRANEAL patients than in control patients, were peritonitis, upper respiratory infec
most common treatment-related adverse event for EXTRANEAL patients was skin ra
have been reported in the post-marketing setting and are detailed in the full prescribir

General Peritoneal Dialysis-Related
Encapsulating Peritoneal Sclerosis (EPS) is a known, rare complication of peritoneal
reported in patients using peritoneal dialysis solutions including EXTRANEAL. Infrequ
been reported.

Aseptic technique should be used throughout the peritoneal dialysis procedure to redu
such as peritonitis.

Fluid status, hematologic indices, blood chemistry, and electrolyte concentrations, inc
sodium, magnesium and bicarbonate, should be monitored periodically. Abnormalities
should be treated promptly under the care of a physician.

Overinfusion of peritoneal dialysis solution volume into the peritoneal cavity may be c
distention, feeling of fullness and/or shortness of breath. Treatment of overinfusion is
solution from the peritoneal cavity.

Treatment should be initiated and monitored under the supervision of a physician kno
of patients with renal failure.

Please see Full Prescribing Information.

Please see Medication Guide.

EXTRANEAL is a trademark of Baxter International Inc., its affiliates or subsidiaries.

For More Information

EXTRANEAL Package Insert (pdf 684k)
Peritoneal Dialysis
Kidney Failure
Price Lists and Product Catalog
(pdf 3.4M)

Renal Clinical Helpline
1-888-736-2543, Option #2

Exter
www
www
You
REN
4.

**2006年4月改訂（第6版）
*2005年6月改訂

JLRMDIPIDOOS

Baxter

貯　法	室温保存（ただし，直射日光を避ける。また，バッグを破るおそれがあるので凍結を起こさない場所で保存する。）
使用期限	2年（最終使用年月をバッグ及び外箱に表示。）
注　意	「取扱い上の注意」の項参照

日本標準商品分類番号	87342	
薬価基準収載	ダイアニールPD-2 1.5	16200AMY00314000
	ダイアニールPD-2 2.5	16200AMY00315000
	ダイアニールPD-2 4.25	16200AMY00316000
薬価収載		
排液用バッグなし		
（規格：500mL，1000mL，1500mL，2000mL）		1987年11月
（規格：5000mL）		1994年 7月
排液用バッグ付		
（規格：1000mL，1500mL，2000mL）		1992年12月
（規格：2500mL）		2000年 7月
販売開始		
排液用バッグなし		
（規格：500mL，1000mL，1500mL，2000mL）		1988年 3月
（規格：5000mL）		1995年 1月
排液用バッグ付		
（規格：1000mL，1500mL，2000mL）		1993年 2月
（規格：2500mL）		2001年 3月
再審査結果		1992年12月

release date

腹膜透析液

処方せん医薬品注)*

ダイアニール PD-2 1.5
ダイアニール PD-2 2.5
ダイアニール PD-2 4.25

【禁　忌】（次の患者には投与しないこと）

1. 横隔膜欠損のある患者［胸腔へ移行し，呼吸困難が誘発されるおそれがある］
2. 腹部に挫滅傷又は熱傷のある患者［挫滅又は熱傷の治癒を妨げるおそれがある］
3. 高度の腹膜癒着のある患者［腹膜の透過効率が低下しているため］
4. 尿毒症に起因する以外の出血性素因のある患者［出血により蛋白質失が亢進し，全身状態が悪化するおそれがある］
5. 乳酸代謝障害の疑いのある患者［乳酸アシドーシスが誘発されるおそれがある］

【組成・性状】

1. 組成

＜成分・分量（w/v%）＞

品目＼成分	ブドウ糖 ($C_6H_{12}O_6$)	塩化ナトリウム (NaCl)	乳酸ナトリウム ($C_3H_5NaO_3$)	塩化カルシウム ($CaCl_2 \cdot 2H_2O$)	塩化マグネシウム ($MgCl_2 \cdot 6H_2O$)
ダイアニールPD-2 1.5	1.36	0.538	0.448	0.0257	0.00508
ダイアニールPD-2 2.5	2.27	0.538	0.448	0.0257	0.00508
ダイアニールPD-2 4.25	3.86	0.538	0.448	0.0257	0.00508

＜電解質濃度＞

品目	ブドウ糖 (g/dL)	電解質（mEq/L）				
		Na^+	Ca^{2+}	Mg^{2+}	Cl^-	乳酸イオン
ダイアニールPD-2 1.5	1.36	132	3.5	0.5	96	40
ダイアニールPD-2 2.5	2.27	132	3.5	0.5	96	40
ダイアニールPD-2 4.25	3.86	132	3.5	0.5	96	40

2. 性状

ダイアニールPD-2 1.5，ダイアニールPD-2 2.5及びダイアニールPD-2 4.25はいずれも無色～微黄色の澄明な液で，無臭である。

＜浸透圧，pH＞

品目	総浸透圧(mOsm/L)（理論値）	浸透圧比（生理食塩液に対する比）	pH
ダイアニールPD-2 1.5	346	約1.1	4.5～5.5
ダイアニールPD-2 2.5	396	約1.3	4.5～5.5
ダイアニールPD-2 4.25	485	約1.6	4.5～5.5

注）注意－医師等の処方せんにより使用すること*

【効能・効果】

慢性腎不全患者における腹膜透析（高マグネシウム血症や代謝性アシドーシスの改善が不十分な場合に用いる）。

＜効能・効果に関連する使用上の注意＞

ダイアニール 1.5，2.5，4.25，ダイアニールPD-2　1.5，2.5，4.25及びダイアニールPD-4　1.5，2.5，4.25は，各々次のような場合に使用すること。

ダイアニール 1.5，2.5，4.25

i）血清マグネシウム値が正常域下限以下の場合や代謝性アシドーシスの過度の是正が認められる場合

ii）糖代謝障害や肝障害のある場合

ダイアニールPD-2　1.5，2.5，4.25

高マグネシウム血症や代謝性アシドーシスの改善が不十分な場合

ダイアニールPD-4　1.5，2.5，4.25

高マグネシウム血症や代謝性アシドーシスの改善が不十分で，かつ炭酸カルシウム製剤や活性型ビタミンD製剤の投与により高カルシウム血症をきたすおそれのある場合

【用法・用量】

腹腔内に注入し透析治療を目的とした液として使用する。通常，成人では1回1.5～2Lを腹腔内に注入し4～8時間滞液し効果期待後に排液除去する。以上の操作を1回とし体液の過剰が1kg/日以下の場合，通常，1日あたりダイアニールPD-2 1.5のみ3～4回の連続操作を継続して行う。体液の過剰が1kg/日以上認められる場合，通常，ダイアニールPD-2 2.5を1～4回またはダイアニールPD-2 4.25を1～2回処方し，ダイアニールPD-2 1.5と組み合せて1日あたり3～5回の連続操作を継続して行う。なお，注入量，滞液時間，操作回数は，症状，血液生化学値及び体液の平衡異常，年齢，体重などにより適宜増減する。注入及び排液速度は，通常300mL/分以下とする。

＜用法・用量に関連する使用上の注意＞

1. ダイアニールPD-2　1.5は患者の体液の過剰が1kg/日以下の場合，これのみを1日に3～4回交換使用すること。ダイアニールPD-2　2.5は患者の体液の過剰が1kg/日以上の場合に通常1日に1～4回処方し，ダイアニールPD-2　1.5と組み合せて交換使用すること。ダイアニールPD-2　4.25は高浸透圧液であり，これのみを使用する場合には脱水を起こすことがあるので，急速な除水や多量の除水を必要とする時で，患者の体液の過剰が1kg/日以上の場合に，通常，1日に1～2回処方し，ダイアニールPD-2　1.5と組み合せて交換使用すること。体液過剰の状況は，患者の体重と基準体重とを比較検討し決定する。基準体重は浮腫がなく，細胞外液の過剰に基づくと考えられる心不全等の症状がない状態で測定した体重値である[1]。

2. 本剤の2.5Lは2L貯留を施行しているCAPD患者で透析不足による全身倦怠感，食欲不振，不眠等の尿毒症症状が認められる場合，又は1日5回以上の透析液交換に不都合を感じている場合に，患者の腹腔内容積や肺活量に応じて（体重60kg以上を目安とする）2Lに代え適用する。

【使用上の注意】

1. 慎重投与（次の患者には慎重に投与すること）

(1) 腹膜炎，腹膜損傷，腹膜癒着及び腹腔内臓器疾患の疑いのある患者［腹膜炎，腹膜損傷，腹膜癒着及び腹腔内臓器疾患が悪化又は誘発されるおそれがある］
(2) 腹部手術直後の患者［手術部位の治癒を妨げるおそれがある］
(3) 糖代謝障害の疑いのある患者［糖代謝異常が悪化又は誘発されるおそれがある］
(4) ジギタリス治療中の患者［ジギタリス中毒が誘発されるおそれがある］
(5) 食事摂取が不良の患者［栄養状態が悪化するおそれがある］
(6) 腹部ヘルニアのある患者［腹部ヘルニアが悪化するおそれがある］
(7) 腰椎障害のある患者［腰椎障害が悪化するおそれがある］
(8) 憩室炎のある患者［憩室炎が腹膜炎合併の原因となるおそれがある］
(9) 人工肛門使用患者［細菌感染を起こすおそれがある］
(10) 利尿剤を投与している患者［水及び電解質異常が誘発されるおそれがある］
(11) 高度の換気障害のある患者［胸腔圧迫により換気障害が悪化するおそれがある］
(12) 高度の脂質代謝異常のある患者［高コレステロール血症，高トリグリセライド血症が悪化するおそれがある］
(13) 高度の肥満がみられる患者［肥満を増長させるおそれがある］
(14) 高度の低蛋白血症のある患者［低蛋白血症が悪化するおそれがある］
(15) ステロイド服用患者及び免疫不全患者［易感染性であるため］

2. 重要な基本的注意

(1) 注入液，排液の出納に注意すること。
(2) 本剤の投与開始は，医療機関において医師により，又は医師の直接の監督により実施すること。通院，自己投与は，医師がその妥当性を慎重に検討し，十分な教育訓練を施したのち，医師自らの管理指導の下に実施すること。
(3) 腹膜炎を合併することがある[2]ので，本剤の投与にあたっては特に清潔な環境下で無菌的操作により行うとともに次のことに注意すること。
　1) 腹膜カテーテルの管理及び腹膜カテーテル出口部分の状態には十分注意すること。
　2) 腹膜炎が発生すると排液が濁るので，その早期発見のために，毎排液後，液の混濁状態を確認すること（腹膜炎発生時の液の混濁状態は正常排液2,000mLに対して牛乳1mLを添加した液の混濁状態を参考とすることができる）。
(4) 長期の腹膜透析実施において硬化性被嚢性腹膜炎（SEP）を合併することがある[3]ので，発症が疑われたら直ちにCAPDを中止し，血液透析に変更すること。発症後は経静脈的高カロリー輸液を主体とした栄養補給を行い，腸管の安静を保つ。嘔吐がある場合は胃チューブにより胃液を持続吸引する。本症は必ずイレウス症状を伴うが，診断には次の臨床症状，血液検査所見及び画像診断が参考になる。
　臨床症状：低栄養・るいそう・下痢・便秘・微熱・血性排液・局所性もしくはびまん性の腹水貯留・腸音ぜん動音低下・腹部における塊状物触知・除水能の低下・腹膜透過性の亢進
　血液検査所見：末梢白血球数の増加・CRP陽性・低アルブミン血症・エリスロポエチン抵抗性貧血・高エンドトキシン血症
　画像診断：X線検査・超音波検査・CT検査
(5) 定期的に血液生化学検査及び血液学的検査等を実施すること。

3. 副作用

国内で実施された臨床試験（20施設78症例）及び市販後調査（38施設195症例）で対象とされた総計273例のうち副作用として報告された症例数は59例であった。主な副作用は高コレステロール血症22件（8.1%），高トリグリセライド血症20件（7.3%）であった。（再審査終了時）

(1) **重大な副作用**（類薬：ダイアニール1.5, 2.5, 4.25）
（心・血管障害）
急激な脱水による循環血液量の減少，低血圧，ショック等があらわれることがあるので，このような場合には本剤の投与を中止し，輸血，生理食塩液，昇圧剤の投与等適切な処置を行うこと。
(2) **その他の副作用**
副作用が認められた場合には，投与の中止等必要に応じて適切な処置を行うこと。

	頻度不明※	5%以上（発現件数率）	5%未満（発現件数率）
循環器			高血圧
電解質・酸塩基平衡	低カリウム血症，低ナトリウム血症，低カルシウム血症，低リン血症，高乳酸血症		低マグネシウム血症，代謝性アルカローシス
消化器	悪心，腹痛，下痢，便秘，痔核		嘔吐，食欲不振，腹部膨満感
代謝・栄養		高コレステロール血症，高トリグリセライド血症	低蛋白血症，高血糖，肥満
その他	息切れ，胸水貯留，アミノ酸や水溶性ビタミン等の喪失，発熱		筋痙攣，除水不良，ヘルニア，陰嚢水腫

※頻度不明の副作用は，本剤の臨床試験及び市販後調査では認められなかったが，類薬（ダイアニール 1.5, 2.5, 4.25）で認められた副作用及び本剤の配合成分組成あるいは作用から予測される副作用を記載した。

4. 妊婦，産婦，授乳婦等への投与

妊婦・産婦・授乳婦に対する安全性は確立していないので，妊婦又は妊娠している可能性のある婦人，産婦あるいは授乳婦には，治療上の有益性が危険性を上回ると判断される場合にのみ投与すること。

5. 適用上の注意

(1) 静脈内に投与しないこと。
(2) 下痢，腹痛，悪寒等の予防のため，本剤をあらかじめ体温程度に温めてから注入すること。
(3) 本剤はカリウムを含まないため，血清カリウム値が正常あるいは低値の場合，またジギタリス治療中の患者では症状に応じて本剤中のカリウム濃度が1～4mEq/Lになるよう補正して使用すること。

【臨床成績】[4,5]

国内で実施された臨床試験（20施設，解析対象69例）及び市販後調査（38施設，195例）で得られた成績の概要は次のとおりである。

1. 尿毒症症状改善効果
尿毒症症状の改善効果に対する検討は各症例毎に月1回判定する方法により行われ，4～5段階評価で「改善」（著明改善及び改善）以上又は「中等度改善」（著明改善及び中等度改善）以上を改善として集計し，改善率を算出した。成人の場合，臨床試験と市販後調査の成績を合わせると99.6%（238症例3450箇月〈検討数〉で「改善」又は「中等度改善」以上3436箇月〈検討数〉），小児の場合，市販後調査の成績より98.4%（26症例495箇月〈検討数〉で「改善」以上487箇月〈検討数〉）の改善率であった。
2. 高マグネシウム血症改善効果
高マグネシウム血症に対する検討は69例に対して，1日あたり3～5バッグ（2L/バッグ）を3箇月間連続投与して実施された。ダイアニールでは改善率75.3%であったが，ダイアニールPD-2では改善率100.0%を示した。
3. 代謝性アシドーシス改善効果
代謝性アシドーシスに対する検討は69例に対して，1日あたり3～5バッグ（2L/バッグ）を3箇月間連続投与して実施された。ダイアニールでは改善率89.9%であったが，ダイアニールPD-2では改善率98.6%を示した。
4. 除水効果
2Lの透析液を4～8時間排液した場合，各ブドウ糖濃度の透析液における除水量は，ダイアニールPD-2とダイアニールとで有意な差は認められず，ダイアニールPD-2　1.5で172±100mL（平均値±標準偏差，61症例），ダイアニールPD-2　2.5で453±151mL（平均値±標準偏差，29症例），ダイアニールPD-2　4.25で970±215mL（平均値±標準偏差，30症例）であった。ダイアニールPD-2とダイアニールにおいて，各ブドウ糖濃度の透析液の総浸透圧はほぼ同じであるため除水量も同じと考えられる。ただし，除水量は患者の血漿浸透圧，水分摂取状況，残存腎機能（尿量）等により変動するものと考えられる。

【薬効薬理】[6,7,8,9]

ダイアニールPD-2は腎によって通常排泄される毒物や代謝物の除去，また体液及び電解質液平衡の是正を目的として腹腔内へ腹膜カテーテルを通じて注入し，一定時間経過後排液するものである。浸透と拡散は透析液と患者の血漿間の腹膜を介して行われる。これにより，血漿電解質濃度は拡散により正常域に近づき，また血中に高濃度で存在する毒物や代謝物は腹膜を介して透析液に移動する。ダイアニールPD-2はダイアニールよりマグネシウムを低く，重炭酸の前物質である乳酸を高く調整してあるので，高マグネシウム血症及び代謝性アシドーシスが更に是正される。透析液中のブドウ糖により血漿と比較して高浸透圧にすることで浸透圧勾配をつくり，患者から腹腔内に水を除去する。

【取扱い上の注意】

1. 誤用を避けるため，他の外箱カートンへ入れ替えないこと。
2. 幼児の手の届かないところへ保管すること。
3. 外袋は水蒸気の過度の透過を防ぐためのものであるため，万一，破れている場合は使用しないこと。
4. 外袋内に水滴が観察されるが，蒸気滅菌の為であり，液漏れによるものではない。
5. フランジブルシールは折れやすいので取扱いに注意すること。また，使用前に折れている場合は使用しないこと。
6. ポートやチューブをバッグからはがす時に，バッグを破り，液漏れを起こすおそれがあるので丁寧にはがすこと。
7. バッグにスパイクを押入する際に，ポートを突き破ることがないように注意して行うこと。
8. 低温で注液をすると腹痛を起こすおそれがあるため，製品は専用の医療用加温器を用いて，体温程度に用時加温すること。
9. 注液準備手順及びツインバッグ操作方法の概略（詳細については必ず対象医療用具の取扱説明書及び操作手順マニュアルを参照のこと）
   (1) 交換準備がすべて整ってから，外袋を破って開封し，本剤を取り出す。
   (2) 液が無色～微黄色の透明で異常が認められないこと，及び各部の接合が完全であることを確認すること。そうでない場合は無菌性が損なわれているおそれがあるので使用しないこと。
   (3) バッグを強く押して漏れの有無を調べること。また，同時にチューブに亀裂がないか確認すること。万一漏れやチューブの亀裂がみられる場合には無菌性が損なわれているおそれがあるので使用しないこと。
   (4) 容器下部の注入口から保護キャップを取り除き，患者側チューブ又は対象医療用具の注・排液セットと接続する。
   (5) バッグ上部の穴を用いて，容器をつり下げ注液する。
   (6) ツインバッグの注・排液方法は次のとおり行う。
   患者側の接続チューブ先端のキャップを外す。本品の接続チューブコネクターを患者側の接続チューブ先端と接続する。腹腔内貯留液を本品の排液側チューブ経由で排液バッグに排出する。排出後，患者側の接続チューブをクランプし，本品の薬液充填バッグの液流出口のフランジブルシールを開放し，新しい透析液で回路内を洗浄し，排液側チューブ経由で排液バッグに流す。その際，チューブの亀裂や漏れがみられる場合には，使用を中止し，医師又はその他医療従事者に連絡すること。
   次に，本品の排液側チューブをクランプし，患者側の接続チューブのクランプを外して，新しい透析液を腹腔内に注入する。注入後患者側の接続チューブと本品の接続チューブコネクターとの接続を外す。患者側の接続チューブ先端にキャップを取り付けて交換操作を完了する。
10. 在宅医療にて本品を使用する場合は以下の注意事項を参考にすること。
   (1) バッグの交換操作はマニュアルに従って行わせること。
   (2) トラブル発生時の対処法は，次の表を参考にすること。

トラブル	対処法
フランジブルシール開放後の透析液バッグ及びチューブの亀裂又は液漏れ	直ちにクランプを閉め，新しいキャップをして，医師又はその他医療従事者に連絡し，指示を受けてください。
接続部及びチューブの亀裂又は液漏れ	直ちに亀裂又は液漏れの発生部分より，患者側に近い接続チューブを2又は3か所しばり，医師又はその他医療従事者に連絡し，指示を受けてください。

【包　装】

品目	規格	容器	包装単位
ダイアニールPD-2 1.5	500mL	1Lバッグ	12袋
	1000mL	1Lバッグ	8袋
	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
	5000mL	5Lバッグ	2袋
ダイアニールPD-2 2.5	500mL	1Lバッグ	12袋
	1000mL	1Lバッグ	8袋
	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
	5000mL	5Lバッグ	2袋
ダイアニールPD-2 4.25	500mL	1Lバッグ	12袋
	1000mL	1Lバッグ	8袋
	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
ダイアニールPD-2 1.5 システムII	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
	5000mL	5Lバッグ	2袋
ダイアニールPD-2 2.5 システムII	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
	5000mL	5Lバッグ	2袋
ダイアニールPD-2 4.25 システムII	1500mL	2Lバッグ	6袋
	2000mL	2Lバッグ	4袋
ダイアニールPD-2 1.5† ツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋
	2500mL	3Lバッグ	4袋
ダイアニールPD-2 2.5† ツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋
	2500mL	3Lバッグ	4袋
ダイアニールPD-2 4.25† ツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋
ダイアニールPD-2 1.5† UVフラッシュツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋
	2500mL	3Lバッグ	4袋
ダイアニールPD-2 2.5† UVフラッシュツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋
	2500mL	3Lバッグ	4袋
ダイアニールPD-2 4.25† UVフラッシュツインバッグ	1000mL	2Lバッグ	6袋
	1500mL	2Lバッグ	4袋
	2000mL	2Lバッグ	4袋

†薬価基準収載名：（排液用バッグ付）

【主要文献】

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【文献請求先】**

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製造販売元**
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DIANEAL PD-2 PERITONEAL DIALYSIS SOLUTION WITH DEXTROSE - dextrose, sodium chloride, sodium lactate, calcium chloride and magnesium chloride injection, solution
Baxter Healthcare Corporation

DESCRIPTION

DIANEAL PD-2 peritoneal dialysis solutions in AMBU-FLEX containers are sterile, nonpyrogenic solutions for intraperitoneal administration only. They contain no bacteriostatic or antimicrobial agents or added buffers.
Composition, calculated osmolarity, pH, and ionic concentrations are shown in Table 1.
Potassium is omitted from DIANEAL solutions because dialysis may be performed to correct hyperkalemia. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.** Frequent monitoring of serum electrolytes is indicated.
Because average plasma magnesium levels in some chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.
Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983) have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.
The osmolarities shown in Table 1 are calculated values. As an example, measured osmolarity by freezing point depression determination of DIANEAL PD-2 peritoneal dialysis solution with 1.5% dextrose is approximately 334 mOsmol/L, compared with measured values in normal human serum of 280 mOsmol/L.
The plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Peritoneal dialysis is a procedure for removing toxic substances and metabolites normally excreted by the kidneys, and for aiding in the regulation of fluid and electrolyte balance.
The procedure is accomplished by instilling peritoneal dialysis fluid through a conduit into the peritoneal cavity. With the exception of lactate, present as a bicarbonate precursor, electrolyte concentrations in the fluid have been formulated to attempt to normalize plasma electrolyte concentrations resulting from osmosis and diffusion across the peritoneal membrane (between the plasma of the patient and the dialysis fluid). Toxic substances and metabolites, present in high concentrations in the blood, cross the peritoneal membrane into the dialyzing fluid. Dextrose in the dialyzing fluid is used to produce a solution hyperosmolar to the plasma, creating an osmotic gradient which facilitates fluid removal from the patient's plasma into the peritoneal cavity. After a period of time (dwell time), the fluid is drained from the cavity.

INDICATIONS AND USAGE

Peritoneal dialysis is indicated for patients in acute or chronic renal failure when nondialytic medical therapy is judged to be inadequate (Vaamonde and Perez 1977). It may also be indicated in the treatment of certain fluid and electrolyte disturbances, and for patients intoxicated with certain poisons and drugs (Knepshield et al. 1977). However, for many substances other methods of detoxification have been reported to be more effective than peritoneal dialysis (Vaamonde and Perez 1977; Chang 1977).

CONTRAINDICATIONS

None known

WARNINGS

Peritoneal dialysis should be done with great care, if at all, in patients with a number of abdominal conditions including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, and large polycystic kidneys (Vaamonde and Perez 1977). Other conditions include recent aortic graft replacement and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.
An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences including congestive heart failure, volume depletion, and shock.

Excessive use of DIANEAL PD-2 peritoneal dialysis solution with 3.5% or 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.
In acute renal failure patients, plasma electrolyte concentrations should be monitored periodically during the procedure. Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of blood chemistries and hematologic factors, as well as other indicators of patient status.
Because average plasma magnesium levels in chronic CAPD patients have been observed to be elevated (Nolph et al. 1981), the magnesium concentration of this formulation has been reduced to 0.5 mEq/L. Average plasma magnesium levels have not been reported for chronic IPD and CCPD patients. Serum magnesium levels should be monitored and if low, oral magnesium supplements, oral magnesium containing phosphate binders, or peritoneal dialysis solutions containing higher magnesium concentrations may be used.
Because average serum bicarbonate levels in some chronic CAPD patients (Nolph et al. 1981), some chronic IPD patients (La Greca et al. 1980), and some chronic CCPD patients (Diaz-Buxo et al. 1983), have been observed to be somewhat lower than normal values, the bicarbonate precursor (lactate) concentration of this formulation has been raised to 40 mEq/L. Serum bicarbonate levels should be monitored.
Not for use in the treatment of lactic acidosis.
Potassium is omitted from DIANEAL PD-2 solutions because dialysis may be performed to correct hyperkalemia. **Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.**
The use of 5 or 6 liters of dialysis solution is not indicated in a single exchange.
Refer to manufacturer's directions accompanying drugs to obtain full information on additives.
If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.
After the pull ring has been removed, inspect connector of solution container for fluid flow. A few drops of solution within the connector or pull ring may be present due to condensation of water resulting from the sterilization process. If a continuous stream of fluid is noted, discard solution because sterility may be impaired.
After removing overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard the solution because the sterility may be impaired.
Freezing of solution may occur at temperatures below 0°C (32°F). Do not flex or manipulate container when frozen. Allow container to thaw naturally in ambient conditions and thoroughly mix contents by shaking.

PRECAUTIONS

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection. If peritonitis occurs, the choice and dosage of antibiotics should be based upon the results of identification and sensitivity studies of the isolated organism(s) when possible. Prior to identification of the involved organism(s), broad-spectrum antibiotics may be indicated.
Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.
Significant losses of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Animal reproduction studies have not been conducted with DIANEAL peritoneal dialysis solutions. It is also not known whether DIANEAL peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DIANEAL peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Do not administer unless solution is clear and seal is intact.

ADVERSE REACTIONS

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a chronic peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure. Solution related adverse reactions may include electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome, and muscle cramping.

DOSAGE AND ADMINISTRATION

DIANEAL PD-2 solutions are intended for intraperitoneal administration only.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
The mode of therapy (Intermittent Peritoneal Dialysis [IPD], Continuous Ambulatory Peritoneal Dialysis [CAPD], or Continuous Cyclic Peritoneal Dialysis [CCPD]), frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for and supervising the treatment of the individual patient.
To avoid the risk of severe dehydration and hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with the lowest level of osmolarity consistent with the fluid removal requirements for that exchange.
Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. (See Directions for Use)
The addition of heparin to the dialysis solution may be indicated to aid in prevention of catheter blockage in patients with peritonitis, or when the solution drainage contains fibrinous or proteinaceous material (Ribot et al. 1966). 1000 to 2000 USP units of heparin per liter of solution has been recommended for adults (Furman et al. 1978). For children, 50 units of heparin per 100 mL of dialysis fluid has been recommended (Irwin et al. 1981).
Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

Intermittent Peritoneal Dialysis (IPD)
For maintenance dialysis of chronic renal failure patients.
The cycle of instillation, dwell and removal of dialysis fluid is repeated sequentially over a period of hours (8 to 36 hours) as many times per week as indicated by the condition of the patient. For chronic renal failure patients, maintenance dialysis is often accomplished by periodic dialysis (3 to 5 times weekly) for shorter time periods (8 to 14 hours per session) (Mattocks and El-Bassiouni 1971).

Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cyclic Peritoneal Dialysis (CCPD)
For maintenance dialysis of chronic renal failure patients.
In CAPD, 1.5 to 3.0 liters of dialysis solution (depending upon patient size) are instilled into the peritoneal cavity of adults and the peritoneal access device is then clamped (Kim et al. 1984; Twardowski and Janicka 1981; Twardowski and Burrows 1984). For children, 30 to 50 mL/kg body weight with a maximum of 2 liters has been recommended (Potter et al. 1981; Irwin et al. 1981).
The solution remains in the cavity for dwell times of 4 to 8 hours during the day and 8 to 12 hours overnight. At the conclusion of each dwell period, the access device is opened, the solution drained and fresh solution instilled. The procedure is repeated 3 to 5 times per day, 6 to 7 days per week. Solution exchange volumes and frequency of exchanges should be individualized for adequate biochemical and fluid volume control (Moncrief et al. 1982; Twardowski et al. 1983). The majority of exchanges will utilize 1.5% or 2.5% dextrose containing peritoneal dialysis solutions, with 3.5% or 4.25% dextrose containing solutions being used when extra fluid removal is required. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978).
In CCPD, the patient receives 3 or 4 dialysis exchanges during the night which range from 2-1/2 to 3 hours dwell duration. Typically 1.5 to 2.0 liters of dialysis solution (depending upon patient size) are delivered each cycle by an automatic peritoneal dialysis cycler machine. After the last outflow during the night, an additional exchange is infused by the cycler machine into the peritoneum. The equipment is then disconnected from the patient, and the dialysate remains in the peritoneum for 14 to 15 hours during the day until the next nocturnal cycle (Diaz-Buxo et al. 1981). Combinations of 1.5% or 2.5% dextrose containing peritoneal dialysis solutions are usually used for the nighttime exchanges, while 3.5% or 4.25% dextrose is used when extra fluid removal is required such as during the daytime exchange. Patient weight is used as the indicator of the need for fluid removal (Popovich et al. 1978) so therapy should be individualized according to the patient's need for ultrafiltration.
It is recommended that adult patients being placed on chronic peritoneal dialysis or, in the case of pediatric patients, the selected caretaker, (as well as the patient, when suitable), should be appropriately trained in a program which is under the supervision of a physician. Training materials are available from Baxter Healthcare Corporation, Deerfield, IL 60015, USA to facilitate this training.

HOW SUPPLIED
DIANEAL PD-2 peritoneal dialysis solutions in AMBU-FLEX II and AMBU-FLEX III containers are available in nominal size flexible containers with fill volumes and dextrose concentrations as indicated in Table 1.
All DIANEAL PD-2 peritoneal dialysis solutions have overfills which are declared on container labeling.
Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77°F): brief exposure up to 40°C (104°F) does not adversely affect the product.

Directions for Use
Use aseptic technique.
For complete system preparation, see directions accompanying ancillary equipment.
Peritoneal dialysis solutions may be warmed in the overpouch to 37°C (98.6°F) to enhance patient comfort. However, only dry heat (for example, heating pad) should be used. Solutions should not be heated in water due to an increased risk of infection. Microwave ovens should not be used to heat solutions because there is a potential for damage to the solution container. Moreover, microwave

oven heating may potentially cause overheating and/or non-uniform heating of the solution that may result in patient injury or discomfort.

To Open
Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. If supplemental medication is desired, follow directions below before preparing for administration. Check for minute leaks by squeezing container firmly.

To Add Medication
Additives may be incompatible.
If the resealable rubber plug on the medication port is missing or partially removed, do not use product if medication is to be added.
1. Put on mask. Clean and/or disinfect hands.
2. Prepare medication site using aseptic technique.
3. Using a syringe with a 1 inch long 19 to 25 gauge needle, puncture resealable medication port and inject medication.
4. Position container with ports up and evacuate the medication port by squeezing and tapping it.
5. Mix solution and medication thoroughly.

Preparation for Administration
1. Put on mask. Clean and/or disinfect hands.
2. Place solution container on work surface.
3. Remove pull ring from connector of the solution container. If continuous fluid flow from connector is observed, discard solution container.
4. Remove tip protector from tubing set and immediately attach to connector of the solution container.
5. Continue with therapy set-up as instructed in user manual or directions accompanying tubing sets.
6. Upon completion of therapy, discard unused portion.

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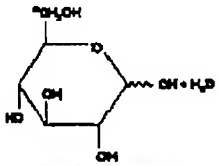
Table 1.

Composition/ 100 mL						Osmolarity	pH	Ionic Concentration (mEq/L)						How Supplied	
*Dextrose Hydrous USP ($C_6H_{12}O_6 \cdot H_2O$)	Sodium Chloride USP (NaCl)	Sodium Lactate USP ($C_3H_5NaO_3$)	Calcium Chloride USP ($CaCl_2 \cdot 2H_2O$)	Magnesium Chloride USP ($MgCl_2 \cdot 6H_2O$)	(mOsmol/L) (calc)		Sodium	Calcium	Magnesium	Chloride	Lactate	Fill Volume (mL)	Container Size (mL)	Code	NDC
Dianeal PD-2 Peritoneal Solution with 1.5% Dextrose **AMBU-FLEX II** CONTAINER	538 mg	448 mg	25.7 mg	5.08 mg	346	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 2500 3000 5000 6000	1000 3000 3000 3000 6000 6000	L5B5163 L5B5166 L5B5168 L5B5169 L5B5193 L5B9710	NDC 0941-0411-05 NDC 0941-0411-06 NDC 0941-0411-08 NDC 0941-0411-04 NDC 0941-0411-07 NDC 0941-0411-11
Dianeal PD-2g Peritoneal Solution with 1.5% Dextrose **AMBU-FLEX III** CONTAINER	538 mg	448 mg	25.7 mg	5.08 mg	346	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1500 2000 2500 3000 5000 6000	500 1000 1000 1000 2000 2000 3000 3000 5000 6000	5B5160 5B5161 5B5162 5B5163 5B5165 5B5166 5B5168 5B5169 5B5193 5B9710	NDC 0941-0411-40 NDC 0941-0411-41 NDC 0941-0411-42 NDC 0941-0411-43 NDC 0941-0411-45 NDC 0941-0411-46 NDC 0941-0411-48 NDC 0941-0411-49 NDC 0941-0411-25 NDC 0941-0411-28
Dianeal PD-2g Peritoneal	538 mg	448 mg	25.7 mg	5.08 mg	396	5.2 (4.0 to	132	3.5	0.5	96	40	1000 2000 2500	1000 3000 3000	L5B5173 L5B5177 L5B5178	NDC 0941-0413-05

Dialysis Solution with 2.5% Dextrose AMBU-FLEX II CONTAINER						6.5)						3000 5000 6000	3000 6000 6000	L5B5179 L5B5194 L5B9711	NDC 0941-0413-06 NDC 0941-0413-08 NDC 0941-0413-04 NDC 0941-0413-07 NDC 0941-0413-01
Dianeal PD-2g Peritoneal Solution with 2.5% Dextrose AMBU-FLEX III CONTAINER	2.58	538 mg	448 mg	25.7 mg	5.08 mg	396	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1000 1500 2000 2500 3000 5000 6000	500 1000 1000 1000 2000 2000 3000 3000 3000 5000 6000	5B5170 5B5171 5B5172 5B5173 5B5174 5B5175 5B5177 5B5178 5B5179 5B5194 5B9711	NDC 0941-0413-40 NDC 0941-0413-41 NDC 0941-0413-42 NDC 0941-0413-43 NDC 0941-0413-44 NDC 0941-0413-45 NDC 0941-0413-47 NDC 0941-0413-48 NDC 0941-0413-49 NDC 0941-0413-25 NDC 0941-0413-28
Dianeal PD-2g Peritoneal Solution with 3.5% Dextrose	3.86	538 mg	448 mg	25.7 mg	5.08 mg	447	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	2500	3000	5B4804	NDC 0941–0423–48
Dianeal PD-2g Peritoneal Dialysis Solution with 4.25% Dextrose AMBU-FLEX II CONTAINER	4.29	538 mg	448 mg	25.7 mg	5.08 mg	485	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	1000 2000 2500 3000 5000 6000	1000 3000 3000 3000 6000 6000	L5B5183 L5B5187 L5B5188 L5B5189 L5B5195 L5B9712	NDC 0941-0415-05 NDC 0941-0415-06 NDC 0941-0415-08 NDC 0941-0415-04 NDC 0941-0415-07 NDC 0941-0415-01
Dianeal PD-2g Peritoneal Solution with	4.29	538 mg	448 mg	25.7 mg	5.08 mg	485	5.2 (4.0 to 6.5)	132	3.5	0.5	96	40	250 500 750 1000 1000 1500	500 1000 1000 1000 2000 2000	5B5180 5B5181 5B5182 5B5183 5B5184 5B5185	NDC 0941–0415–40 NDC 0941-0415-41 NDC 0941-0415-42

4.25% Dextrose AMBU-FLEX III CONTAINER												2000 2500 3000 5000 6000	3000 3000 3000 5000 6000	5B5187 5B5188 5B5189 5B5195 5B9712	NDC 0941-0415-43 NDC 0941-0415-44 NDC 0941-0415-45 NDC 0941-0415-47 NDC 0941-0415-48 NDC 0941-0415-49 NDC 0941-0415-25 NDC 0941-0415-28



Dextrose Hydrous, USP

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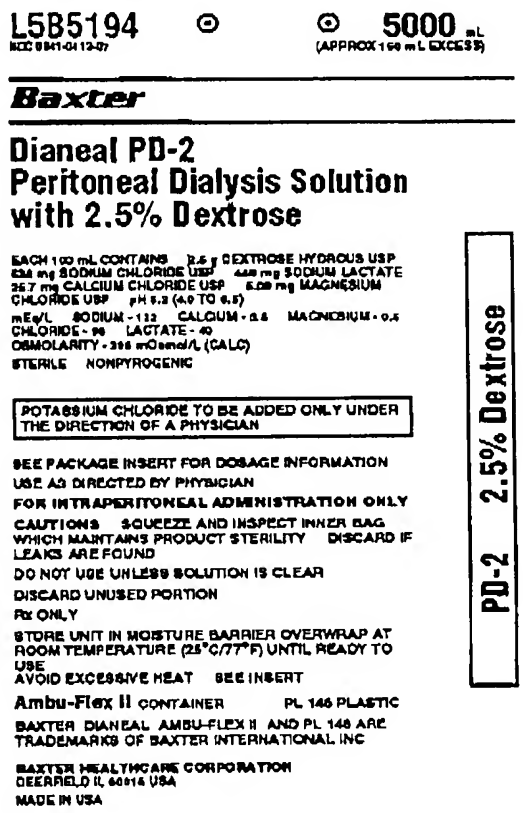
PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

Container Label



Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose 5000 mL Container Label

L5B5194
NDC 0941-0413-07
5000 mL
(APPROX 150 mL EXCESS)
Baxter
Dianeal PD-2
Peritoneal Dialysis Solution
with 2.5% Dextrose
EACH 100 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
538 mg SODIUM CHLORIDE USP 448 mg SODIUM LACTATE
25.7 mg CALCIUM CHLORIDE USP 5.08 mg MAGNESIUM
CHLORIDE USP pH 5.2 (4.0 TO 6.5)
mEq/L SODIUM - 132 CALCIUM - 3.5 MAGNESIUM - 0.5
CHLORIDE - 96 LACTATE - 40
OSMOLARITY - 396 mOsmol/L (CALC)
STERILE NONPYROGENIC
POTASSIUM CHLORIDE TO BE ADDED ONLY UNDER
THE DIRECTION OF A PHYSICIAN
SEE PACKAGE INSERT FOR DOSAGE INFORMATION
USE AS DIRECTED BY PHYSICIAN
FOR INTRAPERITONEAL ADMINISTRATION ONLY
CAUTIONS SQUEEZE AND INSPECT INNER BAG
WHICH MAINTAINS PRODUCT STERILITY DISCARD IF

LEAKS ARE FOUND
DO NOT USE UNLESS SOLUTION IS CLEAR
DISCARD UNUSED PORTION
Rx ONLY
STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25OC/77OF) UNTIL READY TO USE
AVOID EXCESSIVE HEAT SEE INSERT
Ambu-Flex II CONTAINER PL 146 PLASTIC
BAXTER DIANEAL AMBU-FLEX II AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA

Carton Label

DIANEAL PD-2 2.5% DEX PERITONEAL DIALYSIS SOLN
AMBU-FLEX II CONT
2-5000ML
SECONDARY BAR CODE
(17) YYMM00 (10) XXXXX
PRIMARY BAR CODE
2.5%
(01) 50309410413079
L5B5194
LOT XXXXX
EXP XXXXX

Dianeal PD-2 Pertioneal Dialysis Solution with 2.5% Dextrose Ambu-Flex II 5000 mL Carton Lubel

DIANEAL PD-2 2.5% DEX PERITONEAL DIALYSIS SOLN
AMBU-FLEX II CONT
2-5000ML
2.5%
SECONDARY BAR CODE
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